FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS: None

CLASS II RECALLS:

6515NS
MDC 13215 Infusion Pumps
PRODUCT IVAC Space Saver Volumetric Infusion Pumps: a) Model 597; b) Model 598; c) Model 599. Recall #Z-300/302-8.
CODE All serial numbers.
MANUFACTURER Alaris Medical Systems, Inc. (formerly IVAC Corp.), San Diego, California.
RECALLED BY Alaris Medical Systems, Inc., San Diego, California, by letter dated April 11, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 28,000 units were distributed.
REASON The devices are subject to over infusion due to the wear of the camming surfaces, causing the opening of the IV tubing to become smaller, therefore, reducing the loading gap.

[ ] None Present
[ ] Action Taken _____
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6515NS
MDC 14361 Ventilators, Intensive Care, Neonatal/Pediatric
PRODUCT Bear Cub Infant Pressure Infant Ventilator, Model 750vs. Recall #Z-333-8.
CODE All serial numbers.
MANUFACTURER Dale Electronics, Tempe, Arizona (component supplier).
RECALLED BY Allied Healthcare Products, Inc., Ventilation Products Division, Riverside, California, by fax beginning on March 10, 1997, followed by letter. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 338 units were distributed.
REASON The potentiometer may become unstable making setting the controls difficult or impossible.

[ ] None Present
[ ] Action Taken _____
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6515NS
MDC 13215 Infusion Pumps
UPDATE Recall Z-039/040-8, Horizon/Horizon Nxt Modular Infusion Pumps which appeared in the November 19, 1997 Enforcement Report is being rescinded. Completion of B. Braun McGaw's investigation determined that the devices were

not defective, but that the test method used was causing the erroneous results. On November 16.1997 the firm notified all users that the pumps performed within spec. The recall numbers will be reassigned.

CLASS III RECALLS: None

MEDICAL EQUIPMENT SAFETY ALERTS: None

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.
Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than 17 APR 98 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN).
(AFMLO/FOM-P, Bonnie Phillips, DSN 343-7445)

CLASS I RECALLS:

NSN	6505 Nonstandard
PRODUCT	Entuss-D Jr (Hydrocodone Bitartrate 2.5 mg/Pseudoephedrine Hydrochloride 30 mg), Pediatric Expectorant Antitussive and Nasal Decongestant, Rx, in 4 fluid ounce bottles. NDC #59441-439-04. Recall #D-078-8.
CODE	Lot #J960855A EXP 10/98.
MANUFACTURER	Mikart, Inc., Atlanta, Georgia (contract manufacturer).
RECALLED BY	Roberts Pharmaceutical Corporation, Eatontown, New Jersey (responsible firm), by press release on January 30, 1998, followed by letter. Firm-initiated recall ongoing.
DISTRIBUTION	Eastern United States.
QUANTITY	538 bottles were distributed.
REASON	Misbranding - Incorrect label dosage instructions for adults which may lead to an overdose situation.

[ ] None Present

[ ] Action Taken _____

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CLASS I I RECALLS:

NSN	6505 Nonstandard
PRODUCT	Levothroid Tablets (Levothyroxine Sodium Tablets, USP), 75 mcg, in 100 count bottles, Rx, for replacement or substitution therapy for diminished or absent thyroid function. NDC #0456-0322-01. Recall #D-066-8.
CODE	Lot #99618.
MANUFACTURER	Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
RECALLED BY	Forest Pharmaceuticals, Inc., subsidiary of Forest Laboratories, Inc., St. Louis, Missouri, by letter dated January 16, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	12,382 bottles were distributed.
REASON	Low tablet weights (subpotent).

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	Cedax (ceftibuten for oral suspension), 120 ml (when reconstituted) 90 mg/5 ml). NDC #0085-0777-02. Recall #D-075-8.
CODE	Lot #7710411 EXP 8/99.
MANUFACTURER	Schering Corporation, Miami Lakes, Florida. Recalled by Schering Laboratories, Schering Plough Corporation, Kenilworth, New Jersey, by letter dated January 14, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	4,252 bottles were distributed.
REASON	Subpotency due to low fill.

[ ] None Present
[ ] Action Taken _____

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NSN	6515 Nonstandard
PRODUCT	Techstar XL 6 French Percutaneous Vascular Surgery Device (PVS), indicated for the percutaneous delivery of sutures for closing the common femoral artery access site of patients who have undergone diagnostic catherization procedures using 5 to 6 Fr. Sheaths: a) Catalog No. TXL-431-06; b) Catalog No. TXLS-432-06.

Recall #Z-311/312-8.

CODE 1563 1641 1713 1720 1776 1564 1700 1714 1722 1778 1632 1704 1717 1727 1779 1634 1705 1718 1774 1497 1565 1671 1673 1711 1060 1091 1130 1363 1369 1559 1062 1093 1135 1364 1552 1561 1063 1102 1143 1366 1552 1068 1089 1107 1362 1367 1557 1098.

MANUFACTURER Perclose, Inc., Menlo Park, California.

RECALLED BY Manufacturer, by letter faxed on November 22, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 3,933 units were distributed.

REASON The product was manufactured with out-of-specification components.

[ ] None Present
[ ] Action Taken _____

NSN 6515 Nonstandard

PRODUCT Sterile ENT Knives and Burs in a plastic tray with lids and sealed in a primary peep pouch: a) MICRO ENT KNIVES, List No. A907060, Model Nos. 14-58230, 14-58231, 14-58232, 14-58234; b) MICRO-CRAFT AND HELIX BURS, List No. A871727, Model Numbers with the following common prefixes: "31-xxxx" and "9xxx-++". Recall #Z-327/328-8.

CODE a) All lots manufactured from August 11, 1997 to November 6, 1997; b) All lots manufactured from August 11, 1997 to November 6, 1997.

MANUFACTURER Xomed Surgical Products, Inc., Jacksonville, Florida.

RECALLED BY Manufacturer, by letter on November 12, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY Approximately 22,856 units were distributed.

REASON The sterility of the devices has been compromised as evidenced by loss of package integrity.

[ ] None Present
[ ] Action Taken _____

NSN 6515 Nonstandard

PRODUCT Implants for Retinal Detachment Surgery: a) Circling Band 240-Style 2.5 5/Box, Catalog No. E5381 700; b) Non Sterile Band, Catalog No. NSE5381-700, c) Silicone Strip 219-Style

	Grv 4.5 5/Box, Catalog No. E5381 710, d) Non Sterile Silicone Strip, Catalog No. NSE5381-710. Recall #Z-320/323-8.
CODE	Lot numbers: a) MH72550; b) 97246; MH73580; d) 97246.
MANUFACTURER	Vesta, Inc., Franklin, Wisconsin.
RECALLED BY	Storz Instrument Company, St. Louis, Missouri, by letter dated January 6, 1998, and by fax on January 7 and 13, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	a) 2,085 implants; b) 200 implants; c) 235 implants; d) 5 implants were distributed.
REASON	The products do not meet the firms requirements for elongation and may exhibit cracks or may break when stretched.

[ ] None Present
[ ] Action Taken _____

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NSN	6550 Nonstandard
PRODUCT	Isolate Sperm Separation Media, intended for use as a human sperm separation medium for intra-uterine insemination (IUI): a) Catalog #99257 b) Catalog #99258 c) Catalog #99264 (2x50 mL) #99264 (12x16 mL) d) Catalog #99275 Lot #9927570906. Recall #Z-314/317-8.
CODE	a) Lot #9925770911; b) Lot #9925870911 c) Lot #9926471016 (2x50 mL); Lot #9926471017 (12x16 mL) d) Lot #9927570906.
MANUFACTURER	Irvine Scientific, Santa Ana, California.
RECALLED BY	Manufacturer, by telephone and letter on December 22, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Arizona, California, Connecticut, Illinois, Indiana, Michigan, Nebraska, New York, Pennsylvania, Rhode Island, Texas, Washington state.
QUANTITY	a) 40 bottles; b) 93 boxes; c) 27 boxes; d) 39 bottles were distributed.
REASON	Products were found to be contaminated with fungus.

[ ] None Present
[ ] Action Taken _____

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NSN	6550 Nonstandard
PRODUCT	a) Renasol Liquid Bicarbonate Concentrate BC-1-L Part B in one gallon (3.78 liter) bottles; b) Naturalyte 9000 Liquid Bicarbonate Concentrate in one gallon (3.78 liter) bottles, product catalog number 08-9990-6, a bicarbonate dialysis concentrate, which is mixed with an acid concentrate and water to produce dialysate for hemodialysis. Recall #Z-318/319-8.
CODE	a) Part B: Lot 03J702, MFD 09 97, EXP 03 99 b) Lot 67K707, MFD 10 97, EXP 04 99.
MANUFACTURER	Minntech Corporation, Minneapolis, Minnesota.
RECALLED BY	Manufacturer, by telephone on January 16, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	2,416 cases (4 gallons per case) were distributed.
REASON	Concentrate contains mold.

[ ] None Present
[ ] Action Taken _____

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CLASS I I I RECALLS:

NSN	6505 Nonstandard
PRODUCT	Caffeine and Sodium Benzoate Injection, USP, 0.5 g/2 ml, Rx sterile solution for intramuscular or slow intravenous administration to treat respiratory depression associated with overdosage with CNS depressant drugs. NDC #11098-505-02. Recall #D-057-8.
CODE	Lot #101406.
MANUFACTURER	Taylor Pharmaceuticals, Decatur, Illinois.
RECALLED BY	Manufacturer, by letter dated November 25, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Canada.
QUANTITY	366 cartons were distributed; firm estimated that 33 percent of product remained on market at time of recall initiation.
REASON	Mislabeling - The ampule label and shelf carton fail to list the strength of the caffeine and sodium benzoate. Also, the shelf carton lists the ampule size as 2 ml on the principle display panel and 1 ml the end flap.

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	Hydroxyzine Hydrochloride Syrup, USP, in 16 ounce and 1 gallon containers, for symptomatic relief of anxiety and tension, under the Alpharma, Schein, Barre, and Rugby labels. Recall #D-068-8.
CODE	Lot numbers: RA6017, RA6018, RF6315, RJ6429, RL6634, RP6815, RS6895, RC7179, RD7245, RD7246, RH7425, RK7583, RL7683.
MANUFACTURER	Alpharma, U.S. Pharmaceuticals Division, Baltimore, Maryland.
RECALLED BY	Manufacturer, by letter dated January 15, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	Firm estimated that 132,206 units remained in commerce at time of recall initiation.
REASON	Subpotent.

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	a) Acetylcysteine Solution, USP 20% (200 mg/ml) 30 ml vials, packaged in units of 3, Rx, Mucolytic; for bronchial indications such as asthma and tuberculosis. NDC #0517-7630-03 b) Concentrated Sodium Chloride Injection, USP, 23.4% (234 mg/ml) in 30 ml single dose vials, Rx, additive in parenteral fluid therapy for use in patients who have problems with Sodium electrolytic intake or excretion. NDC #0517-2930-23. Recall #D-071/072-8.
CODE	Lot numbers: a) 7855 EXP 5/99; b) 7846 EXP 11/99.
MANUFACTURER	American Regent Laboratories, Inc., Shirley, New York.
RECALLED BY	Manufacturer, by fax on January 6, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	a) 44,097 vials; b) 163,375 vials were distributed; firm estimated that a) 75-80 percent; b) 80 percent of the product remained on market at time of recall initiation.
REASON	Mispackaging - Correctly labeled concentrated sodium chloride injection vials placed into intermediate cartons labeled as Acetylcysteine Solution.

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	Scopolamine Hydrobromide Injection, USP, 0.4 mg/ml in 1 ml multiple dose vials. Recall #D-073-8.
CODE	Lot #360116 EXP 2/28/99.
MANUFACTURER	Fujisawa USA, Inc., Grand Island, New York.
RECALLED BY	Fujisawa USA, Inc., Deerfield, Illinois, by letter issued dated January 26, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	137,650 vials were distributed.
REASON	Subpotent (stability).

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	Epinephrine Injection, USP 1:1000 (1mg/ml), 1 mL ampule, sterile, Rx, intramuscular or subcutaneous liquid injection, preservative free. Packaged in boxes of 25 x 1 mL ampules. A sympathetic, vaso-constricting, ommetic drug commonly used to relieve respiratory distress due to bronchospasm, to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and to prolong action of infiltration anesthetics. May restore cardiac rhythm. NDC# 0517-1071-25. Recall #D-076-8.
CODE	Lot Numbers: 6487 EXP 1/98, 6654 EXP 2/98, 6862 EXP 5/98, 7278 EXP 10/98, 7414 EXP 11/98, 7415 EXP 11/98, 7424 EXP 11/98, 7471 EXP 12/98, 7659 EXP 2/99, 7728 EXP 3/99, 7783 EXP 4/99, 6738 EXP 3/98, 6972 EXP 6/98, 7040 EXP 7/98 7126 EXP 8/98.
MANUFACTURER	American Regent Laboratories, Inc., Shirley, New York.
RECALLED BY	Manufacturer, by letter on January 23, 1998, followed by telephone. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	715,575 ampules were distributed.
REASON	Discoloration - Product fails color and clarity specifications.

[ ] None Present
[ ] Action Taken _____

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NSN	6505 Nonstandard
PRODUCT	ARTH-Rx (Methyl Nicotinate 0.5% Capsaicin 0.025%) Topical Analgesic Lotion, in 3 ounce units, for the temporary relief of minor aches and pains of muscles and joints. Recall #D-077-8.
CODE	All lots on the market.
MANUFACTURER	Phillips Pharmatech Labs, Inc., Largo, Florida (responsible firm).
RECALLED BY	Phillips Gulf Corporation, Largo, Florida, by letter dated December 12, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	North Carolina, Florida, Georgia, Texas, Pennsylvania, New York, Illinois, California.
QUANTITY	12,456 bottles were distributed.
REASON	Product fails to bear an expiration date.

[ ] None Present
[ ] Action Taken _____

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NSN	6515 Nonstandard
PRODUCT	Triumph Vascular Access Ports: a) SSA-16-I Triumph 1 Vascular Access Ports, b) 8 SSD-16-I Triumph Vascular Access Ports. RECALL #Z-293/294-8.
CODE	Lot numbers: a) 50717D; b) 524126B.
MANUFACTURER	ACT Medical, Inc., Walthlam, Massachusetts.
RECALLED BY	Horizon Medical Products, Inc., Manchester, Georgia, by telephone on February 21, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	a) 39 ports; b) 166 ports were distributed.
REASON	The devices were packaged with a size 8 French Introducer instead of size 10 French Introducer as labeled.

[ ] None Present
[ ] Action Taken _____

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NSN	6515 Nonstandard
PRODUCT	2-0 Chromic Gut Suture (3.5 Metric), DT-12 37mm 27" 67 cm), Sterile, Type C, Absorbable, Surgical Suture USP, Diamond Point. Recall #Z-313-8.
CODE	Lot #951824.
MANUFACTURER	Sherwood-Davis & Geck, Manati, Puerto Rico.
RECALLED BY	Sherwood-Davis & Geck, Hazelwood, Missouri, by letter dated December 16, 1997, followed by visit. Firm-initiated recall ongoing.
DISTRIBUTION	New York, Illinois, Connecticut, Louisiana,

	Puerto Rico, Georgia.
QUANTITY	59 cartons were distributed.
REASON	Some of the foil envelopes containing the sutures were labeled Chromic Gut Size 3-0 but actually contained size 2-0.

[ ] None Present
[ ] Action Taken _____

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NSN	6550 Nonstandard
PRODUCT	Gliadel Wafer (Polifeprosan 20 with Carmustine Implant), 7.7 mg carmustine/wafer, in units of 8 wafers individually packaged, Rx indicated for use as a adjunct to surgery to prolong survival in patients with recurrent glioblastoma multiform for whom surgical resection is indicated. NDC #IS 0075-9995-0107. Recall #D-065-8.
CODE	Lot #K97A1.
MANUFACTURER	Guilford Pharmaceuticals, Inc., Baltimore, Maryland.
RECALLED BY	Rhone Poulenc Rorer Pharmaceuticals, Inc., Collegeville, Pennsylvania, by telephone on December 12, 1997, followed by letter dated December 16, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	41 units (8 wafers each) and 17 partial units (less than 8 wafers) remained on market at time of recall initiation.
REASON	Excess breakage of wafers.

[ ] None Present
[ ] Action Taken _____

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